REF YB500046	**TGS TA HSV 1/2 IgM** ***Control Set***	
INSTRUCTIONS FOR USE	IVD +2°C +8°C	CE

INTENDED USE

The TGS TA HSV (Herpes Simplex Virus) 1/2 IgM Control Set is used to control the quality of the TGS TA HSV type 1 and 2 IgM assays performed with the *TGS TA* Analyser.

SUMMARY AND EXPLANATION

Control samples containing at least two different concentrations of analyte must be used regularly to guarantee the validity of the results obtained each day.

The TGS TA HSV 1/2 IgM Control Set contains a human serum:

- Anti HSV 1 and 2 IgM Negative (concentration lower than 10 UA/mL)

and a human serum

- Anti HSV 1 and 2 IgM Positive (concentration higher than 10 UA/mL)

The controls supplied in the Control Set are used to monitor the accuracy and precision of the assay of anti HSV 1 and 2 IgM antibodies performed with the TGS TA Analyser.

WARNINGS AND PRECAUTIONS

The reagents supplied in the TGS TA HSV 1/2 IgM Control Set are only for in vitro diagnostic use and not for in vivo use in humans or animals.

This product must be used by professional users in strict compliance with the instructions given in this document.

The control sera supplied in the Control Set are not specific for each lot of kits, but can be used with kits from different lots.

Technogenetics cannot be held responsible for any losses or damages caused by use not in conformity with the instructions supplied.

Safety precautions

This product contains material of human origin.

All units of serum or plasma used to produce the Control Set components have been analysed with FDA-approved methods and found not to be reactive due to presence of HBsAg, anti-HCV, anti-HIV1 and anti-HIV2.

However, since no analysis method is able to guarantee the absence of pathogenic agents, all material of human origin must be considered to be potentially infected and handled as such.

In the event of damaged packaging or accidental leakage, decontaminate the area concerned with a diluted solution of sodium hypochlorite after putting on suitable personal protective equipment (overall, gloves, goggles).

Dispose of the material use for the clean-up and of the packaging involved in the leakage according to national regulations for disposal of potentially infected waste.

The control sera contain sodium azide as a preservative. Since sodium azide may react with lead, copper and leaded brass forming explosive azides in piping, it is recommended that reagents or waste are not poured down drains but are disposed of in compliance with the national regulations on disposal of potentially hazardous waste.

Operating precautions

Reliable results can only be obtained by strictly complying with these instructions and carefully following what is written in the user manual for the analyser.

Do not use the control sera after their expiry date.

MATERIALS AND REAGENTS

Materials and reagents supplied

CONTROL	-	3 X 1.5 mL

Human serum Negative for anti-HSV 1 and anti-HSV 2 IgM antibodies containing Sodium Azide (< 0.1 %) as preservative.

- 3 vials each containing 1.5 mL of serum.

CONTROL	+	3 X 1.5 mL

Human serum Positive for anti-HSV 1 and anti-HSV 2 IgM antibodies containing Sodium Azide (< 0.1 %) as preservative.

- 3 vials each containing 1.5 mL of serum.

DATA DISK

Mini-CD containing all the information and data related to the products in the TGS TA Line.

Materials and reagents required but not supplied in the kit:

- TGS TA HSV 1/2 IgM Cod. No. YB500029
- TGS TA Top Cap Set Cod. No. YC500010
  300 red top caps to close the calibrator containers after first use.

REAGENT STORAGE AND STABILITY

Store the reagents supplied in the kit at 2-8°C in a vertical position in a dark place.
In these conditions unopened control sera are stable until their expiry date.
After the first use, the control sera remain stable for 60 days if they are stored at 2-8°C, and if they are not left in the analyser for more than 1 hour per session.
Do not freeze the control sera.

OPERATING PROCEDURE

Carefully follow the instructions given in the user manual of the analyser to obtain reliable analytical results.

Loading of controls
TGS TA controls are ready for use. Leave the controls at room temperature for 10 minutes and then gently shake the contents, either manually or using a vortex, avoiding the formation of foam. Do not turn the vial upside down.
When using the controls for the first time, remove the guarantee seal and the white sealing cap before placing them in the analyser.
If the controls have already been used, the container will have a top cap (red cap) with no guarantee seal. Remove the red closing cap before placing them in the analyser.
Place the controls in the samples area of the analyser. Please see the user manual for the analyser for identification of the controls by means of the test tube bar-code. If the bar-code is not readable, the identification data may be entered manually.
After the first use, if they are stored at 2-8°C, the control sera remain stable for 60 days if they are not left in the analyser for more than 1 hour per session. The values for the anti-HSV 1/2 IgM antibody concentration in the controls are recorded in the DATA DISK and automatically transferred to the analyser. If the data are not transferred, they may be entered manually.

At the end of the session, the control vials must be closed with the top caps (red caps) provided and stored at 2-8°C until they are used again.

The Data Disk supplied with the Control Set contains information related to all the TGS TA line products updated to the last production lot with the exclusion of products that are out of date when the new Data Disk was compiled. Only the Data Disk with the highest lot number needs to be kept to maintain the information required for correct operation of the system up to date.

Controls must be tested singly once every 24 hours when the test is in use and during each calibration. The values for the control sera must be within the acceptability range specific for the lot. If a control serum is not within the required range, the sample results associated with it cannot be considered to be valid.

In such cases a new calibration must be carried out.

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